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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/029,579	05/06/1998	ULF LANDEGREN	1209-122P	6255

7590 07/29/2003

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EXAMINER

AKHAVAN, RAMIN

ART UNIT PAPER NUMBER

1636

41

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/029,579

Applicant(s)

LANDEGREN, ULF

Examiner

Ramin (Ray) Akhavan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07/11/2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7 and 9-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 9-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 11, 2003 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 7 and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Nilsson et al. Science 265:2085-2088 (1994).

Nilsson and applicant both teach the same composition for targeting nucleic acids, comprising a padlock probe having two free nucleic acid end parts that are partially complementary to and hybridize with neighboring regions of a target nucleic acid sequence. Applicant argues that claim 7 recites a pharmaceutically acceptable carrier that Nilsson neither teaches nor discloses. However Nilsson discloses a ligation buffer comprised of components (tris, ATP, magnesium- and potassium acetate) considered in the art to be pharmaceutically acceptable (figure legend to Figure 4); In support of this inherent characteristic of the buffer additional references were cited in the previous action

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(Paper no. 37, Final Rejection): Rajagopalan et al. (USP 5,162,109 at col. 7, lines 56-68) (teaching tris as pharmaceutically acceptable); Shelley et al (USP 5,505,961 at col. 2, lines 45-64) (teaching carriers comprising potassium acetate as acceptable; Mills (USP 5,132,118 at col. 7, lines 28-68) (teaching carriers comprising potassium and magnesium acetate as acceptable); Rapaport (USP 5,227,371 at col. 5, lines 9-55) (teaching carriers comprising ATP as pharmaceutically acceptable).

Applicant remarks that rejection of claims 7 and 9-12 under 35 U.S.C. §102(b) is improper because the examiner is relying on multiple references to show that the buffer in Nilsson is a pharmaceutically acceptable carrier. This assertion is incorrect because the additional references cited are only to show what is well known in the art and the additional references only reiterate what applicant has admitted in the specification: "The composition is preferably formulated in [admixture] with a suitable carrier, such as conventional pharmaceutically acceptable carriers known in the art." Spec. at 5, lines 34-36.

Normally, only one reference should be used in making a rejection under 35 U.S.C. 102. However, a 35 U.S.C. 102 rejection over multiple references has been held to be proper when the extra references are cited to: Show that a characteristic not disclosed in the reference is inherent. *See* MPEP § 2131.01. The additional references merely show, as applicant admits in the specification, that pharmaceutically acceptable carriers are known in the art. Thus for the aforementioned reasons and for reasons of record the claims 7 and 9-12 are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 contains the phrase “mutually chemically reactive compound” which is neither defined in the specification nor commonly known in the art. Thus the claim is vague and indefinite. As claim 12 is dependent from claim 11, claim 12 is also vague and indefinite.

Applicant asserts that claim 11 and dependent claim 12 are not indefinite because chemical compounds capable of joining the end part of oligonucleotides are well recognized in the art through use of the phrase “mutually chemically reactive compound”. Applicant cites a single reference (Gryaznov et al. Nucleic Acid Res, 22(12):2366-9 (1994)) for support that the phrase above is common in the art, but Gryaznov does not make use of such a phrase. Furthermore, even if Gryaznov did make use of such a term, such use would be insufficient for the phrase to be deemed a term of art, thus well known in the art. For the aforementioned reasoning and reasons of record claims 11 and 12 are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 11 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 11 is drawn to a composition comprising a padlock probe wherein the end part further comprise a mutually chemically reactive compound. This is a genus claim in terms of any mutually chemical reactive compound. The specification does not contain any examples of mutually chemically reactive compounds. Thus the disclosure is not descriptive of the complete structure of a representative number of species, which the claims encompass, as one of ordinary skill in the art cannot envision all mutually chemical reactive compounds based on the teachings in the specification.

Applicant argues that claims 11 and 12 meet the written description requirement because it is commonly known in the art to use chemically reactive compounds to join oligonucleotide ends. Applicant submits Gryaznov for the assertion that chemical compounds and functional groups that are capable of joining the ends of oligonucleotides are well recognized in the art. As discussed above the phrase “mutually chemically reactive compound” is not a term of art and indeed it is not used in Gryaznov.

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Notwithstanding the use or nonuse of the phrase, a single reference showing that autoligation takes place when oligomers hybridize such that two different functional groups on each strand are brought into close proximity is not sufficient basis to support the assertion that one of ordinary skill in the art could know all chemically reactive compounds. Consideration of a reference that does not use the phrase in question does not strengthen applicant's contention. For the aforementioned reasons and reasons of record the claims 11 and 12 are rejected.

Conclusion

Claims 7 and 9-12 are rejected. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114.

Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114.

See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ramin (Ray) Akhavan whose telephone number is 703-305-4454. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

July 24, 2003


DAVID GUZO
PRIMARY EXAMINER